

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON  
BEHALF OF DAVITA, INC. PROPOSING ESTABLISH A NINE-STATION DIALYSIS  
CENTER IN THE CITY OF PORT ORCHARD WITHIN KITSAP COUNTY**

**PROJECT DESCRIPTION**

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services through over 1,200 outpatient centers located in 41 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 369 hospitals throughout the country. [source: DaVita website]

For Washington State, DaVita owns or operates a total of eleven kidney dialysis facilities in Franklin, King, Pierce, and Yakima counties. Below is a listing of the eleven DaVita facilities in Washington. [source: CN historical files]

**Franklin**

Mid-Columbia Kidney Center

**King**

Bellevue Dialysis Center

Federal Way Community Dialysis Center

Kent Community Dialysis Center

Olympic View Dialysis Center

Westwood Dialysis Center

**Pierce**

Lakewood Community Dialysis Center

Puyallup Community Dialysis Center

**Yakima**

Mt. Adams Kidney Center

Union Gap Dialysis Center

Yakima Dialysis Center

This application proposes to establish a nine-station dialysis facility in Kitsap County, to be known as DaVita Port Orchard Dialysis Center (hereinafter referred to as "PODC"). The new dialysis facility will be located within a newly constructed building. As of the writing of this evaluation, the United States Post Office has not assigned the property a physical address. The property is located east of the northeast corner of Bethel Road and Sedgwick Road in Port Orchard. The Kitsap County Assessor parcel number is 0123 013 122 2006.<sup>1</sup> It is noted that DaVita provided a copy of the draft lease agreement for the site. The draft agreement identifies all costs associated with the lease. If this project is approved, the department would include a term requiring DaVita to provide a copy of executed lease agreement between itself and NS Northwest #3, LLC (the lessor). [source: April 24, 2006, supplemental information, p1 and Attachment 3]

The capital expenditure associated with the establishment of the nine-station facility is \$1,042,746, of which 54% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7]

DaVita anticipates that this project would commence immediately after Certificate of Need approval and all nine stations would become operational in December 2007. Under this timeline, year 2008 is the facility's first full year of operation. [source: Application, p8; April 24, 2006, supplemental information, p2]

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<sup>1</sup> There is an existing structure on the land with the address of 1901 SE Sedgwick Road; however the address may change with the new development planned for the site.

## **APPLICABILITY OF CERTIFICATE OF NEED LAW**

This project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

## **CRITERIA EVALUATION**

To obtain Certificate of Need approval, DaVita, Inc. must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment); and 246-310-280 (the dialysis station projection methodology and standards).<sup>2</sup>

## **APPLICATION CHRONOLOGY**

January 1, 2006	Letter of Intent Submitted
February 22, 2006	Application Submitted
February 23, 2006 through May 2, 2006	Department's Pre-Review Activities <ul style="list-style-type: none"><li>• 1<sup>st</sup> screening activities and responses</li></ul>
May 3, 2006	Department Begins Review of the Application <ul style="list-style-type: none"><li>• public comments accepted throughout review</li></ul>
June 9, 2006	Public Hearing Conducted/End of Public Comment
June 26, 2006	Rebuttal Documents Received at Department
August 10, 2006	Department's Anticipated Decision Date
September 5, 2006	Department's Actual Decision Date

## **AFFECTED PERSONS**

Throughout the review of this project, two entities sought and received affected person status under WAC 246-310-010. Both entities are providers of dialysis services within Kitsap County.

- Harrison Medical Center Hospital, an inpatient dialysis provider located in the city of Bremerton;<sup>3</sup> and
- Olympic Peninsula Kidney Center (OPKC), an outpatient dialysis provider located in the cities of Bremerton, Port Orchard, and Poulsbo.

## **SOURCE INFORMATION REVIEWED**

- DaVita's Certificate of Need Application submitted February 22, 2006
- DaVita's supplemental information dated April 24, 2006
- Public comment received throughout the review of the application
- Public hearing documents received at the June 9, 2006, public hearing
- Rebuttal comments provided by DaVita, Inc. received June 26, 2006
- Historical kidney dialysis data obtained from the Northwest Renal Network
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey

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<sup>2</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6).

<sup>3</sup> While Harrison Medical Center sought and received affected person status, it did not provide public comment, attend the public hearing, or provide rebuttal comments related to this application.

### **SOURCE INFORMATION REVIEWED (continued)**

- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from Center for Medicare and Medicaid (CMS) “Dialysis Facility Compare” website (<http://www.medicare.gov/Dialysis/home.asp>).
- Data obtained from the Internet regarding health care providers
- Data obtained from DaVita, Inc.’s webpage (<http://www.davita.com>)
- Data obtained from Gambro AB’s webpage (<http://www.gambro.com>)
- Population data obtained from the Office of Financial Management
- Certificate of Need historical files

### **CONCLUSION**

For the reasons stated in this evaluation, the application submitted by on behalf of DaVita, Inc. proposing to establish a nine-station dialysis center in the city of Port Orchard within Kitsap County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

**A. Need (WAC 246-310-210)**

Based on the source information reviewed, the department determines that the applicant has not met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

The Department of Health's Certificate of Need Program uses the methodology found in WAC 246-310-280 for projecting numeric need for dialysis stations within a county. Using verified facility utilization information obtained from the Northwest Renal Network for the years 2001 through 2005, the department projects the need for dialysis stations to serve the county.

In recent evaluations, the department has evaluated need by examining both linear and non-linear projections of the data. One measure of the accuracy of a regression equation is the determinant of regression, or  $R^2$ .  $R^2$  is a value that describes the relation of actual data to the expected values based on the regression analysis of that data. In general, the closer an equation's  $R^2$  value is to one, the more reliable a regression equation is perceived to be. The department concludes that each value to be estimated should be evaluated using both linear and non-linear regression methods and the regression equation deemed more reliable should be used to predict that data element. In some cases, this will be the non-linear equation; in others, the data may be better described by a linear equation. For those values with small and widely varying numbers, such as the numbers of patients trained for home hemodialysis and peritoneal dialysis, both methods tend to return regression equations with very small  $R^2$  values, indicating that neither method returns a particularly reliable result.

For this project, the department determined that the more reliable determinant of regression, or  $R^2$ , was linear regression projections for the number of dialyses and the number of patients. The non-linear regression projections was determined to be the more reliable determinate for peritoneal training stations.

The first step in performing this regression analysis is to determine the service area of the project. WAC 246-310-010 provides the following definition of the ESRD service area:

*“End-stage renal dialysis (ESRD) service areas means each individual county, designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated, or other service area documented by patient origin.”*

DaVita asserts that while the dialysis center would be located in south Kitsap County; the service area for PODC is Kitsap County as a whole. [source: Application, p3 and p11] Based on the definition above and the ESRD service area defined in previous applications for the existing dialysis centers in the county, the department concurs that the service area is Kitsap County.

The department's projections for Kitsap County are shown in Table I on the following page. [source: Department's methodology based upon Northwest Renal Network facility utilization data-attached to this document as Appendix A.]

**Table I**  
**Department's Dialysis Station Projections**  
**for Kitsap County Based on 2001-2005 Historical Data**

Year	Stations	Existing Capacity	Net Need (Surplus)
2007	35	(subtract) 38 <sup>4</sup>	(3)
2008	37		(1)
2009	39		1
2010	40		2

As shown in Table I above, the department projects a surplus of dialysis stations in Kitsap County for years 2007 and 2008, net need for an additional station in year 2009, and two stations by the end of year 2010.

Using the department's methodology as a starting point and patient origin information for years 2000-2004, DaVita provided its dialysis station projections, which are shown in Table II below. [source: Application, p12]

**Table II**  
**DaVita's Dialysis Station Projections**  
**for Kitsap County Based on 2000-2004 Historical Data**

Year	Stations	Existing Capacity	Net Need (Surplus)
2007	37	(subtract) 35	2
2008	39		4
2009	42		7
2010	44		9

As shown in Table II above, DaVita projects a net need of two stations in Kitsap County for year 2007, which increases to nine stations in the county by the end of year 2010. When comparing DaVita's projections in Table II and the department's projections in Table I, the department concludes the difference in net need can be attributed to the following two factors discussed below.

1) Northwest Renal Network historical data used

The need for additional dialysis stations is determined, in part, by applying the numeric portion of the methodology. The numeric methodology projects the total number of stations needed through a three-year future regression analysis of patient origin adjusted data using the previous five years data. Then the number of existing stations or 'existing capacity' is subtracted from the total number of stations needed, resulting in the number of additional stations needed in a county, or the "net need." When this application was submitted, full year 2005 data was not yet available; therefore, the applicant appropriately used 2000-2004 data. Full year 2005 data became available on June 13, 2006, and the department should appropriately use 2001-2005 data to evaluate this project.<sup>5</sup>

2) Existing capacity subtracted from the total need

As stated above, the methodology requires the number of existing stations or 'existing capacity' to be subtracted from the total number of stations needed, resulting in the

<sup>4</sup>OPKC-Bremerton-19 stations; OPKC-South in Port Orchard-11 stations; and OPKC-Poulsbo-8 stations..

<sup>5</sup> Additionally, a comparison of the 2000-2004 data elements used by both DaVita and the department revealed a discrepancy in the total number of patients that dialyzed in the county counted by DaVita. This discrepancy miscalculates station net need based on 2000-2004 data.

number of additional stations needed in a county, or the “net need.” As shown in Table II above, DaVita subtracted 35 existing stations from the total stations needed, resulting in a net need beginning in year 2007. In its count of stations, DaVita did not count the three training stations in operation at OPKC-Bremerton, thereby counting only 16 stations, rather than 19 at that facility.

The methodology requires the count of all dialysis stations at facilities within the ESRD service area. All stations include incenter stations, training stations, and stations that are CN approved, but not yet operational. As a result, DaVita did not include all stations when determining ‘existing capacity’ of the service area.

In summary, using the results shown in Table I above, the department projects a surplus of dialysis stations in Kitsap County for years 2007 and 2008, need for one additional station in year 2009, and a net need of two stations by the end of year 2010. Based on the methodology shown in Table I, the numeric need for additional stations in the Kitsap County service area does not support approval of this project. A review of the remaining standards under WAC 246-310-280 follows.

WAC 246-310-280(4) requires that the existing dialysis centers that would stand to lose market share by approval of a project, must be operating at 80% capacity of a 3-patient shift, per non-training station, per year, before additional stations may be added. Within its application, DaVita acknowledges that Kitsap County is considered one service area. There are three facilities located within the county--OPKC-Bremerton; OPKC-Port Orchard; and OPKC-Poulsbo. For this standard, it is critical to review the most current data available which would reflect the reality of a new facility operating in the service area. For this project, the most current data is the June 2006 quarterly data obtained from the Northwest Renal Network. Table III below summarizes the utilization for the all three facilities. [source: Year 2005 audited NRN data; and June 2006, Quarterly Utilization Data]

**Table III**  
**Kitsap County Facility Utilization Data**

<b>Facility/Number of Incenter Stations</b>	<b>June 2006</b>
OPKC-Bremerton/16 stations	<b>76.0%</b>
OPKC-Port Orchard/11 stations	<b>72.7%</b>
OPKC-Poulsbo/8 stations <sup>6</sup>	<b>83.3%</b>

As shown in Table III above, based on the most recent Northwest Renal Network data, both OPKC facilities in Bremerton and Port Orchard do not meet the standard defined in WAC 245-310-280(4).<sup>7</sup> This sub-criterion is not met.

As previously stated, within its application, DaVita acknowledges that Kitsap County is considered one service area. The department and DaVita concur on this point. DaVita also asserts, however, that approval of a new facility in Port Orchard would not impact OPKC-Poulsbo, even though the two facilities are within the same service area. DaVita uses a recent HLJ (health law judge) ruling as a basis for this position.<sup>8</sup> The department disagrees

<sup>6</sup> OPKC’s Poulsbo facility became operational on June 19, 2006

<sup>7</sup> Year end 2005 data showed OPKC-Bremerton operating at 93.3%, OPKC-Port Orchard operating at 81.7%, and no utilization for OPKC-Poulsbo because the facility did not become operational until June 2006.

<sup>8</sup> Findings of Fact, Conclusions of Law, and Final Order Upon Reconsideration, Docket #03-09-C-2000CN issued September 16, 2005.

with DaVita's position that a dialysis facility located in the same service area as a proposed facility would not stand to lose market share by approval of the proposed facility. However, it is noted that this argument by DaVita is moot because the Poulsbo facility is operating above the 80% standard as shown in Table III above.

The department must also evaluate whether DaVita projects that PODC would be operating at 80% capacity (748.8 dialyses per non-training station) by the end of year three [WAC 246-310-280(5)] as a nine-station facility. As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement of this project immediately and all nine stations would be operational in December 2007. Under this timeline, year 2008 is the facility's first full year of operation. [source: Application, Appendix 9] DaVita provided its projected utilization as a nine-station facility to be 54% in year 2008; 82% in year 2009, and 95% in year 2010. However, as shown in Table III, OPKC's Poulsbo facility became operational in June 2006. A number of dialysis patients elected to transfer from OPKC's Bremerton and Port Orchard facilities into the Poulsbo facility, which resulted in the Bremerton and Port Orchard facility's utilization to drop below 80%. This lower utilization indicates available stations at both OPKC Bremerton, located within 11 miles of the proposed PODC, and OPKC Port Orchard, located within 3 miles of the proposed PODC. As a result, dialysis station capacity is already available within the ESRD service area; therefore, the department is unable to conclude that DaVita's projections for PODC are reasonable. This sub-criterion is not met.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would be used at the new Port Orchard facility. [source: Application, Appendix 14]

The Admission Policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. The document provided outlines the process/criteria that the dialysis center will use to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission Policy states that any patient with end stage renal disease needing chronic hemodialysis will be accepted to PODC without regard to race, color, national origin, sex, age, religion, or disability. [source: Application, Appendix 14]

To determine whether low income residents would have access to the dialysis services at PODC, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access to the proposed dialysis center, the department uses Medicare certification as the measure to make that determination.

DaVita currently provides services to Medicare and Medicaid eligible patients at its existing eleven dialysis centers and intends to maintain this status. A review of the Indigent Care Policy identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues. Additionally, DaVita demonstrated its intent to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents.

Based on the above information, the department concludes that all residents of the service area would have adequate access to the health services at the proposed Port Orchard Dialysis Center. This sub-criterion is met.

**B. Financial Feasibility (WAC 246-310-220)**

Based on the source information reviewed, the department determines that the applicant has not met the financial feasibility criteria in WAC 246-310-220.

*(1) The immediate and long-range capital and operating costs of the project can be met.*

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the nine-station facility would be operational in December 2007. Based on this timeline, year 2008 would be PODC's first full year of operation.

For financial review of applications, the department requests data for the first three full years following project completion. Using that financial information provided in the application, Table IV illustrates the projected revenue, expenses, and net income for years 2008-2010. [source: Application, Appendix 9]

**Table IV**  
**Port Orchard Dialysis Center**  
**Projected Revenue and Expenses Full Years 2008 - 2010**

	Year One (2008)	Year Two (2009)	Year Three (2010)
# of stations	9	9	9
# of Treatments	4,545	6,916	8,003
# of Patients	31	47	54
% of Occupancy	54.0%	82.1%	95.0%
Net Patient Revenue	\$ 1,301,247	\$ 2,014,366	\$ 2,401,241
Total Operating Expense	\$ 1,260,155	\$ 1,758,277	\$ 2,028,349
Net Profit or (Loss)*	\$ 41,092	\$ 256,089	\$ 372,892
Net Patient Revenue/Treatment	\$ 286.30	\$ 291.26	\$ 300.04
Total Operating Exp./Treatment	\$ 277.26	\$ 254.23	\$ 253.45
Net Profit per Treatment	\$ 9.04	\$ 37.03	\$ 46.59

\*Includes deductions for charity care and bad debt

As shown in Table IV above, at the projected volumes identified in the application, PODC would be operating at a profit in the first three full years of operation as a nine-station facility. However, given that the department concluded in the need section of this evaluation that additional dialysis stations are not needed in the ESRD service area through at least year 2008, the projected number of treatments is likely overstated.

Based on the above information, the department concludes that the project's revenues may be overstated and this sub-criterion is not met.



- (2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

The capital expenditure associated with the establishment of the nine-station facility is \$1,042,746, of which 54% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

*“...Funding from previously allocated operations funds is the least costly approach. Debt financing for this project will not be required since there is sufficient cash on hand. Furthermore, the method of financing would have no impact on the amount charged for each unit of service.”* [source: Application, p16]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in the chart shown below. [source: Application, p16]

Source of Revenue	Percentage of Revenue
Medicare	72%
State (Medicaid)	8%
Insurance/HMO	20%
<b>Total</b>	<b>100%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at PODC. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

However, in the need section of this evaluation, the department concluded that the applicant failed to demonstrate that existing facilities are not available to meet the future need for dialysis services in Kitsap County. Given that the project is not necessary, the department also concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

- (3) The project can be appropriately financed.

As previously stated, the capital expenditure associated with the establishment of the nine-station facility is \$1,042,746, of which 54% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 7% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7] A review of DaVita’s historical financial statements shows the funds necessary to finance the project are available.

Based on the information provided, the department concludes the establishment of PODC would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met

**C. Structure and Process (Quality) of Care (WAC 246-310-230)**

Based on the source information reviewed, the department determines that the applicant has not met the structure and process (quality) of care criteria in WAC 246-310-230.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

To implement this project, DaVita proposes to recruit 7.2 FTEs in full year one (2008), which would increase to a total of 11.8 FTEs by the end of year three (2010). A breakdown of the proposed FTEs is shown in Table V below. [source: Application, p17]

**Table V**  
**Port Orchard Dialysis Center Projected FTEs**

Staff	Year 1 Projected	Year 2 Increase	Year 3 Increase	Total FTEs
Administrator	0.80	0.20	0.00	1.00
Medical Director	Professional Services Contract			
RN	1.60	0.40	0.00	2.00
Patient Care Techs	1.60	0.80	0.80	3.20
Biomedical Techs	0.40	0.10	0.10	0.60
Re-Use Tech	0.40	0.10	0.10	0.60
Administrative Assistant	0.80	0.20	0.00	1.00
MSW	0.30	0.20	0.10	0.60
Dietitian	0.30	0.20	0.10	0.60
LVN	1.00	1.00	0.20	2.20
<b>Total FTE's</b>	<b>7.20</b>	<b>3.2</b>	<b>1.40</b>	<b>11.80</b>

As shown in Table V above, after the initial recruitment of FTEs, DaVita expects a minimal increase in FTEs for PODC through year 2010. DaVita states it expects no difficulty in recruiting staff for PODC because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. [source: Application, p18]

Based on this information, the department concludes that adequate staffing for PODC can be recruited. This sub criterion is met.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing eleven dialysis centers. For PODC, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. Additional services would

be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington. [source: Application, p18]

DaVita acknowledges that since this would be a new facility in Kitsap County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: Application, p18 and Appendix 12]

Based on this information, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. If this project is approved, the department would include a term requiring DaVita to provide a copy of its executed transfer agreement with the local hospital in Kitsap County. Provided that DaVita would agree to the term, this sub-criterion would be met.

(3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,200 centers in 41 states and the District of Columbia. [source: DaVita Webpage] Prior to the October 1, 2005 acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates eleven kidney dialysis treatment centers. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public<sup>9</sup>. To accomplish this task, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the out-of-state facilities where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Besides Washington State, the applicant identified 37 states (including the District of Columbia) that are currently providing patient services. In March 2005, the department surveyed the 37 entities and received responses from 30 states and the District of Columbia<sup>10</sup>. Additionally, only Arizona and Iowa had licensing or survey information available via the internet. Therefore, of the 37 states, the department obtained quality of care history for 32 or 86%, plus the District of Columbia. The compliance history of the remaining states is unknown<sup>11</sup>

For the out-of-state facilities, in all states, with the exception of one facility in Georgia, two in New Jersey, ten in New York, the compliance surveys demonstrated either no enforcement actions or minor non-compliance issues that were acceptable by the states and plans of correction were submitted and implemented.

In Georgia, the East Georgia Dialysis Center was fined \$25,000 for non compliance issues related to continuous quality improvement and long term care plans. In New Jersey, Atlantic City Dialysis Center was fined \$5,000 for non-compliance concerning patient services, medical records and policy and procedure discrepancies. Finally, New York had nine

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<sup>9</sup> WAC 246-310-230(5)

<sup>10</sup> Alabama, California, Colorado, Connecticut, DC, Georgia, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Virginia, Wisconsin and West Virginia

<sup>11</sup> Delaware, Florida, Illinois, Nevada and Utah.

facilities with condition level non-compliance issues that were corrected and implemented and the closure of New York Dialysis Center due to condition level non-compliance.

The department concludes that considering the 665 facilities owned/managed by DaVita, only 13 out-of-state facilities listed above demonstrated substantial non-compliance issues, which equates to less than 2%. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, in the most recent 10 years, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 25 compliance surveys for the DaVita facilities in operation. Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted acceptable plans of correction. [source: facility ownership and survey data provided by the Office of Health Care Survey]

Dmitri Vasin, MD has agreed to provide medical director services at the proposed dialysis center. DaVita provided a copy of the draft medical director agreement between itself and Dr. Vasin. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation for the medical director responsibilities.<sup>12</sup> A review of Dr. Vasin's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Based on DaVita's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the PODC would operate in conformance with state and federal regulations. If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed medical director agreement with Dmitri Vasin, MD. Provided that DaVita would agree to the term, this sub-criterion would be met.

- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

In response to this criterion, DaVita states:

*"The DaVita Quality Improvement Program incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management and process flow. Measurable trend analysis focuses on function and processes. Dialysis specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employment and patient education are integral parts of the program."* [source: Application, page 18]

The above response provided by DaVita does not address how the proposed project will promote continuity of care, not result in unwarranted fragmentation of services for the patients or how the proposed project will have an appropriate relationship with the service area's existing health care system. In order to evaluate this criterion, the department reviewed DaVita's history of providing care to residents in Washington State. The

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<sup>12</sup> The compensation is identified in the pro forma financials provided in the application.

department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Additionally, the department used the most recent utilization data—June 2006--obtained from the Northwest Renal Network to assist in its evaluation of this sub-criterion. According to that data, of the three existing dialysis centers currently operating in the ESRD service area, two are operating below the 80% utilization standard required before additional stations may be added. Based on this information, the department must reasonably conclude that the two facilities would have capacity to serve the patients within Kitsap County. Therefore, the department concludes that approval of this project has the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met.

- (5) *There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.*

This sub-criterion is addressed in sub-section (3) above and is considered met.

#### **D. Cost Containment (WAC 246-310-240)**

Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

- (1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*

Within the application, DaVita provided discussion regarding the following two alternatives to this project. [source: Application, pp19-20]

a) **Do Nothing or Status Quo**

DaVita states that it is committed to establishing facilities in underserved areas, and there were substantial delays caused by on-going litigation related to a new DaVita facility in the ESRD service area. After performing an in-depth analysis and strategy reconfiguration, DaVita determined that need for additional dialysis services still exists in the south area of the county. Based on this rationale, DaVita rejected this option.

b) **Establish a 6-station center in the county**

DaVita provided the following discussion regarding this option.

*“Our original proposal was to develop a 12-station dialysis facility in Poulsbo. The department subsequently reduced the capacity when it approved DaVita to operate a 10-station facility. An administrative law judge reversed the DaVita approval and then reduced the number of stations to 8-stations when the department had found a need for 10 stations. This alternative is different from DaVita’s proposal to establish a 12-station facility in Poulsbo. This is for a six-station center in a different location in the county. Although this may be considered a long term strategy, it does not meet the current needs of the county and growth projections at this time with the growth potential in the county.”*

Based on DaVita’s discussion of the two options above, both options were rejected before submitting this project.

The department recognizes that this project would increase the dialysis station capacity in the county. However, as previously concluded in this evaluation, at this time, the existing number of stations in the service area appears to be adequate. Therefore, on the basis of the information above, the department concludes that adding station capacity to Kitsap County is not the best available alternative at this time, and this sub-criterion is not met.

(2) In the case of a project involving construction:

(a) The costs, scope, and methods of construction and energy conservation are reasonable;

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.